



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/736,004

12/15/2003

Yi Feng Zheng

7459

2953

34500

7590

12/27/2007

DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER

HAQ, SHAFIQUL

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

12/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**UNITED STATES DEPARTMENT OF COMMERCE****U.S. Patent and Trademark Office**

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
10736004	12/15/2003	ZHENG ET AL.	7459

DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER

Shafiqul Haq

ART UNIT	PAPER
1641	20071218

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

A supplemental Examiner's Answer is attached to include the heading (11) "Related Proceeding(s) Appendix" with text.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/736,004
Filing Date: December 15, 2003
Appellant(s): ZHENG ET AL.

Theodore J. Leitereg
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/16/07 appealing from the Office action
mailed 1/24/07.

(1) Real party of interest.

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,041,076	AVENIA	8-1977
EB 2361473 A	ROUHANI	10-2001
EP 1340981 A2	HUI	9-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:
Claims 13,15-19, 21, 24-25, 27 and 30-31 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Hui et al. (EP 1340981 A2) in view of Avenia et al. (US 4,041,076).

Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

Hui et al. disclose various competitive and noncompetitive methods/assays and a kit for detection and quantitative determination of amphetamine derivatives such as MDA, MDMA, MDEA, MDPA, BDB, MBDB etc (paragraphs [0012], [0024], [0029], [0064-0067], [0059] and [0060]) using antibody against amphetamine derivatives and label derivatives (such as fluorescent, luminescent, radioactive isotope etc.) (paragraph [0022]).

Hui's amphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, the

linking group or the position of linker at the amphetamine derivative is different from the present compound.

Avenia et al. disclose amphetamine immunogen, labeled tracer and antibodies (see the teaching of Avenia in above paragraph 5) and disclose competitive immunoassay method for detection of phenethylamines (e.g. norepinephrine, dopamine, epinephrine and amphetamines). The immunogen of Avenia et al. is the same as the immunogen of present application.

Since detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody is available, one would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug.

Therefore, given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia et al in the method of Hui et al, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives.

Claims 13,15-19, 21, 24-25, 27 and 30-31 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Rouhani et al. (GB 2361473 A) in view of Avenia et al. (US 4,041,076).

Claims recite methods, compositions and kits for detecting the presence and/or amounts of entactogens in samples.

Rouhani et al. disclose a method for detection of ecstasy-class analogs. Rouhani discloses preparation of antibody (page 6, lines 19-24; pages 16-18) using the compound conjugated with carrier protein (see abstract) and different homogeneous and heterogeneous immunoassay methods (pages 8-9 and 34) and assay kit (page 31, lines 9-12 and claim 10) for detection and quantitation of ecstasy-class analogs in biological samples (page 22, lines 19-24). Rouhani also discloses the above compound conjugated with a protein to be adapted as immunogen (page 41, example 7). Attachment to a carrier protein or a label is also inherent in the process of immunization (see claims 7 and 8) and immunoassay methods (see pages 8-9 and 34) as disclosed in this reference.

Rouhani's amphetamine and methamphetamine derivatives and immunogens are similar to the compound and immunogen of the present invention and are expected to recognize different amphetamine derivatives suitable for different immunoassays. However, the linking group or the position of linker at the amphetamine derivative is different from the present compound.

Avenia et al. disclose amphetamine immunogen, labeled tracer and antibodies (see the teaching of Avenia in above paragraph 5) and disclose competitive immunoassay method for detection of phenethylamines (e.g. norepinephrine, dopamine, epinephrine and amphetamines). The immunogen of Avenia et al. is the same as the immunogen of present application.

Sine detection of amphetamine, methamphetamine and their derivatives is important in the field of ecstasy drug and once a hapten, immunogen or an antibody is available, one would obviously try to use the hapten and the immunogen in different immunoassay methods to develop a better detection assay for the drug.

Therefore, given the above fact, it would have been obvious at the time of the invention to a person of ordinary skill in the art to substitute equivalent hapten, immunogen or antibody as disclosed by Avenia et al in the method of Rouhani et al, with the expectation of obtaining a similarly useful immunoassay method and kit for detection of amphetamine and amphetamine derivatives.

(10) Response to Argument

Applicant's arguments and amendments filed 7/16/07 have been fully considered, but they are persuasive to overcome the rejections under 35 USC 103.

Appellants' argued that the combined teaching of Hui and Avenia or Rouhani and Avenia is deficient in not disclosing or suggesting at least the following limitation of claim 25 "providing in combination in a medium, together with the sample and the antibodies, an enzyme label conjugate of the formula set forth in the claim having a $-(CH_2)_nC(O)$ moiety linking the enzyme to the molecule". Appellants agree that Avenia discloses hapten conjugates wherein a conventional carrier (Avenia, col 2, ln 10-13) is linked to phenylethylamine

compound by a $-(CH_2)_nC(O)$ moiety. However, Appellants' main argument is that Avenia do not disclose linking a phenethylamine to a label by means of a $(CH_2)_nC(O)$ moiety. Appellants argued that although Avenia states that enzymes may be suitable labels, it is within the context of labeled phenethylamines as disclosed (Avenia, col 4, ln 47-58), namely, labeled derivatives that do not employ a $-(CH_2)_nC(O)$ linking moiety, which is only disclosed for Avenia's novel antigens for forming antibodies. Furthermore, Appellants argued that Avenia is concerned with radiolabeled phenethylamine and antibodies raised against his antigen having a $-(CH_2)_nC(O)$ moiety were clearly superior in all cases to assays utilizing free radical labels and enzyme assays (Avenia, col 11, ln 1-3 and col. 12, ln 1-3) and thus Avenia teaches away labeled conjugate.

This is not found convincing because Avenia clearly discloses that labeled phenethylamine can be used as a competitor in an immunoassay besides using radiolabeled phenethylamine. Avenia, in lines 35-58 of column 4, states:

"The specific antibodies of the present invention are useful as reagents for the determination of phenethylamines of formula I. In such an assay, **known amount of labeled phenethylamine is mixed with the above antibody** and the sample containing phenethylamine is added. The amount of phenethylamines in the sample can be determined by measuring the inhibition of the binding to the specific antibody of the labeled phenethylamine by the unknown sample. The reagents may be added in any order. ----- Suitable labeled phenethylamines for assay purposes include radioisotopically labeled phenethylamines -----
---. **One may also employ phenethylamines labeled with any other unique and detectable label -----**. Other suitable labels include **chromophores, fluorophores, enzymes**, red blood cells, latex particles, etc."

Therefore, Appellants' assertion that Avenia does not disclose labeled phenethylamine conjugate with enzyme and teaches away such conjugates is not correct. Avenia may have preferred radiolabeled phenethylamines as competitors but also suggests usefulness of other labeled conjugate as described above and therefore, Avenia does not teach away using other labeled conjugates. Immunoassays using radiolabeled tracers may be more sensitive but radiolabeled tracers are not always the preferred tracer because of health hazards and there is always a need/search for alternative non radiolabeled detection using tracers or conjugates that are not radio-labeled for carrying out different assays including immunoassays wherein highly sensitive detection is not needed. Therefore, even though Avenia discloses that radioimmunoassay using radiolabeled tracers are more sensitive, cannot be regarded as teaching away of other non-radiolabeled conjugates (e.g. enzyme labeled conjugates). Furthermore, it is noted that all disclosures of non-preferred embodiments must be considered. See *In re Nehsenberg* 126 PQ 383, *In re Boe* 148 PQ 507, *In re Mill & Palmer* 176 PQ 196 (CCPA 1972), *In re Simon* 174 PQ 114 and *In re Lamberti et al.* 192 PQ 278 (CCPA 1976).

Avenia et al. disclose activated hapten (activated with succinimidyl ester)(see formula III), which is capable of conjugating to a carrier protein or to a protein label or a non-protein label. Once an activated hapten is known, it is obvious to one of ordinary skill in the art to conjugate label or carrier at the activated site of the hapten. Since, Avenia discloses detection of phenathethylamine in a sample

using labelled phenethylamine which can be enzyme label (see above discussion) and Avenia discloses activated haptens (see formula III) capable of conjugating to a protein, one of ordinary skill in the art would easily envision conjugating the label (e.g. enzyme label) with the activated hapten.

In response to appellants argument that the combined teachings of the references do not disclose or suggest presently claimed labeled conjugate, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fines*, 837 F.2d 1071, 5USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir.1992). In this case, Avenia discloses activated hapten and also suggested label conjugates with fluorophores, enzymes and latex particle for use in competitive immunoassay and Hui or Rouhani discloses various competitive immunoassay formats for quantitative detection of amphetamine derivatives using antibody against amphetamine (phenethylamine) derivatives and label conjugates. Therefore, since antibody and labeled conjugates are disclosed for phenethylamine , one of ordinary skill in the art would obviously try different immunoassay formats as taught by Hui or Rouhani with the labeled conjugate as suggested by Avenia et al in order to develop a sensitive non-radiolabeled detection assay because Hui or

Art Unit: 1641

Rhouhani are also concerned with the non-radiolabeled immunodetection of phenethylamine in a sample.

For the above reasons, it is believed that the rejections should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

Respectfully submitted,



Shafiqul Haq
Examiner
Art Unit 1641

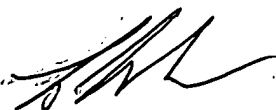
Conferees:

October 24, 2007

Conferees:



Long V. Le
SPE Art Unit 1641



Larry R. Helms
SPE Art Unit 1643